



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 1998

Marilyn M. Chou, Ph.D.
Executive Vice President
Convergent Laser Technologies
a Subsidiary of Xintec Corporation
900 Alice Street
Oakland, California 94607

Re: K981627
Protégé II (tm) Er: YAG Laser System and Accessories
Regulatory Class: II
Product Code: GEX
Dated: May 4, 1998
Received: May 7, 1998

Dear Dr. Chou:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

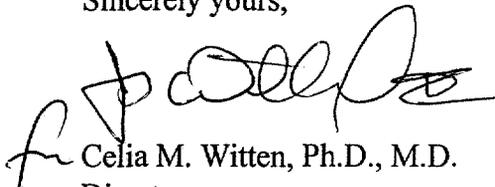
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions does not affect any obligation you might have under sections 531 through 542

of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: #K981627

Device Name: Protégé II (tm) Er:YAG Laser Systems and Accessories (Upgrade)

Indications For Use: The Protégé II Er:YAG Laser Systems and accessories are indicated for the surgical incision/excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, striated and smooth muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands.

Dentistry: Soft tissue (incision, excision, ablation and coagulation)

Dermatology/Plastic Surgery: Indications include epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), debulking benign tumors and cysts, skin resurfacing, superficial skin lesions, and performing diagnostic biopsies.

General Surgery: Indications include surgical incision/excision, vaporization, ablation and coagulation of soft tissue where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation and/or vessel coagulation may be indicated.

Genitourinary: Indications include lesions of the external genitalia, urethra and anus, penis, scrotum and urethra (includes condyloma acuminata, giant perineal condyloma and verrucous carcinoma), vulvar lesions, polyps and familial polyps of the colon.

Gynecology: Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma.

Oral/Maxillofacial: Indications include benign oral tumor, oral and glossal lesions and gingivectomy.

Otorhinolaryngology/Head and Neck (ENT): Indications include ear, nose and throat lesions, polyps, cysts, hyperkeratosis, excision of carcinogenic tissue and oral leukoplakia.

Ophthalmology: Indications include soft tissue surrounding the eye and orbit and anterior capsulotomy.

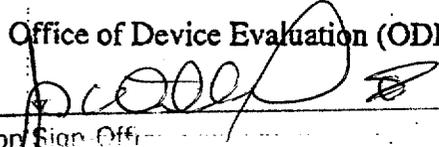
Podiatry: Indications include warts, plantar verrucae, large mosaic verrucae and matrixectomy.

Arthroscopy: Including open and laparoscopic procedures

Orthopedic Surgery

Thoracic Surgery

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of Restorative Devices
 510(k) Number K981627

Prescription Use

OR

Over-The-Counter Use

(21 CFR 801.109)